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10/575,562	04/12/2006	Masato Shirai	KUZ0029US.NP	1387
26259	7590	03/24/2010	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			ORWIG, KEVIN S	
			ART UNIT	PAPER NUMBER
			1611	
			NOTIFICATION DATE	
			03/24/2010	DELIVERY MODE
				ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/575,562	SHIRAI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 December 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3 and 7-10 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3 and 7-10 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/21/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

The amendments and arguments filed Dec. 21, 2009 are acknowledged and have been fully considered. Claims 1-3 and 7-10 are now pending. Claims 4-6 are cancelled; claims 1, 7, and 8 are amended; claim 10 has been added. Claims 1-3 and 7-10 are now under consideration.

### ***OBJECTIONS/REJECTIONS WITHDRAWN***

The objection to claim 7 is withdrawn in light of the claim amendments.

The rejection of claims 5 and 6 under 35 U.S.C. 103(a) is moot in light of the claim cancellations.

The rejection of claims 1-3, 7, and 9 under 35 U.S.C. 103(a) over LIPMAN , KUNIYA, '421, as evidenced by YANO and TABAR is withdrawn in light of the claim amendments.

The rejection of claim 8 under 35 U.S.C. 103(a) over LIPMAN , KUNIYA, '421, as evidenced by YANO and TABAR is withdrawn in light of the claim amendments.

### ***NEW GROUNDS OF OBJECTION/REJECTION***

#### ***Claim Rejections - 35 USC § 112 (1<sup>st</sup> Paragraph)***

**Claims 1-3 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain**

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response filed Dec. 21, 2009 has introduced NEW MATTER into the claims. Amended claim 1 recites the following series of ratios "(15-50)/(25-50)/(30-50)". Support in the instant application is found for the following series ratios "(15-50)/(25-45)/(30-50)". However, written description support is lacking for the instantly recited ratios. In the absence of support for the specific ratios claimed, the series of ratios "(15-50)/(25-50)/(30-50)" in claim 1 is new matter and must be removed from the claims.

Instant claims 1-3 and 7-10 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in amended claim 1, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 1-3 and 7-10 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)***

**Claims 1-3 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The recitation, "petroleum type resin" in claim 1 (lines 11 and 15) renders the claims indefinite. Regarding the term "petroleum type resin", the MPEP states, "The addition of the word "type" to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). Likewise, the phrase "ZSM-5-type aluminosilicate zeolites" was held to be indefinite because it was unclear what "type" was intended to convey. *Ex parte Attig*, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986)."

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-3 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAKAMURA (U.S. 5,770,221; Issued Jun. 23, 1998) in view of YAMAMOTO (U.S. 5,429,591; Issued Jul. 4, 1995).**

1. Nakamura discloses adhesive formulations for percutaneous administration of pharmaceutical agents (title; abstract). The formulations contain a drug, low-molecular weight polyisobutylene (LMW PIB), high-molecular weight polyisobutylene (HMW PIB), an oil, and an styrene-isoprene-styrene (SIS) block copolymer as main bases (abstract; col. 2, lines 51-60). Based on the total amount of the adhesive, the compositions comprise, by weight 1-60 parts LMW PIB, 0.1-40 parts HMW PIB, and 5-50 parts SIS copolymer (col. 2, lines 51-60). By containing the styrene-isoprene-styrene block copolymer, the coagulation power of the adhesive is further improved, and the exudation and the like during storage of the formulation can be prevented (col. 5, lines 30-33). The viscosity average molecular weight of the LMW PIB is from 10,000-100,000 and the viscosity average molecular weight of the HMW PIB 500,000 to 2,500,000 (col. 3, lines 5-11). The vast majority of Nakamura's examples describe embodiments wherein the viscosity average molecular weight of the LMW PIB is less than 70,000 and that of the HMW PIB is greater than 900,000. Nakamura's

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compositions are preferably formed into a base layer on the surface of a backing and covered with a release liner (col. 6, lines 43-46 and line 64 to col. 7, line 3). Suitable materials for the backing/liner include release (e.g. silicone) treated paper, plastics, fluorocarbon polymers, as well as, *inter alia*, polyethylene, aluminum, etc. (col. 6, lines 47-58 and line 64 to col. 7, line 3).

2. Nakamura does not teach the use of polyisoprene separate from the SIS copolymers. However, the use of polyisoprene would have been obvious to a skilled artisan. For instance, Yamamoto discloses adhesive dressings, the adhesives comprising, *inter alia*, polyisobutylene and SIS copolymers. Yamamoto teaches that:

"The rubber-based adhesive preferably is an adhesive which contains polyisobutylene as the base polymer for the adhesive, particularly an adhesive containing a relatively low molecular weight polyisobutylene having a viscosity-average molecular weight of about from 30,000 to 100,000. From the standpoint of imparting cohesive force to the adhesive layer thereby to enable the adhesive layer to maintain the shape retention property and to be free from the problem that part of the adhesive is squeezed out from a side of the adhesive layer, it is preferred that a high molecular weight polyisobutylene having a viscosity-average molecular weight of from 900,000 to 2,000,000 is added, along with the low molecular weight polyisobutylene described above" (col. 4, lines 47-61).

Furthermore, Nakamura teaches:

"It is preferred to sterilize the adhesive layer by subjecting the adhesive layer to irradiation treatment such as irradiation with  $\gamma$ -rays or electron beams. However, where the rubber-based adhesive contains polyisobutylene, it is known that the backbones of the polyisobutylene may be decomposed by irradiation, causing the adhesive composition possibly to liquefy and flow out. Therefore, in order to prevent such a phenomenon, it is preferable that a polymer which, upon irradiation, undergoes not a degradation reaction but a crosslinking reaction, such as natural rubber, polyisoprene, polybutadiene, polyethylene, polypropylene, an ethylene-propylene copolymer, or the like, is added to the adhesive layer in an amount of from 2 to 50% by weight, preferably from 3 to 20% by weight, based on the weight of the rubber-based adhesive. Preferred of these irradiation-crosslinkable polymers are polyisoprene, polybutadiene, and polyethylene." (col. 4, line 64 to col. 5, line 13) (emphasis added)

3. Polyisoprene, especially high-cis-polyisoprene, having a viscosity-average molecular weight of about from 500,000 to 2,000,000, is taught as preferred (col. 5,

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lines 13-18). Thus, one would be motivated to add from 3-20% by weight polyisoprene (taught as preferable by Yamamoto) to Nakamura's composition to prevent decomposition of the polyisobutylene during sterilization.

4. Example 23 of Nakamura describes an embodiment in which the total amount of the HMW PIB and SIS copolymer is 35 parts. Since one would be motivated to add 3-20% polyisoprene, for example, 13% polyisoprene per the teachings of Yamamoto, the total of these three components would be approximately 48 parts. Thus, in using an amount that falls squarely within the teachings of Yamamoto, one of ordinary skill in the art at the time of the invention would have been led to prepare the composition of Nakamura with polyisoprene present in a ratio of ~27 parts, the HMW PIB present in a ratio of ~31 parts, and the SIS present in a ratio of ~42 parts, relative to the other components (i.e. elements (b), (c), and (d) of instant claim 1). Likewise, in the case of Example 23, the LMW PIB is present in a ratio of ~25 parts.

5. Further, Nakamura teaches that the base of the adhesive may contain a tackifying resin, if desired. By adding the tackifying resin, constant releasability may be attained for a long time period without deteriorating the adhesiveness and coagulation power of the base. Petroleum resin is taught as a preferable tackifying resin in the invention, in an amount 50 parts by weight, particularly in the range from 5 to 40 parts by weight, based on the total amount of the formulation (col. 6, lines 5-22). Nakamura also teaches the use of l-menthol as a transdermal enhancer (col. 5, lines 59-61)

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add polyisoprene in the amounts

taught in the prior art, to Nakamura's compositions. One would be motivated to add from 3-20% by weight polyisoprene (taught as preferable by Yamamoto) to Nakamura's composition to prevent decomposition of the polyisobutylene during sterilization. In doing so, one would have had a high expectation of providing a percutaneous composition that is more stable to sterilizing radiation per the teachings of Yamamoto. Applicants are reminded that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, the combination of Nakamura and Yamamoto renders claims 1-3 and 7-10 obvious.

7. Regarding the statement "...thereby exhibiting a removal resistance to water" at the end of claim 1, it is noted that this phrase merely states an inherent property of the composition based on its intended use and is not afforded patentable weight.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a

reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

***Response to Arguments***

Applicants' arguments are moot in light of the new grounds of rejection herein.

***Summary/Conclusion***

Claims 1-3 and 7-10 are rejected; claims 4-6 are cancelled.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin S Orwig/

/David J Blanchard/  
Primary Examiner, Art Unit 1643